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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/524,242	11/29/2005	Sebastien Huron	2002.022 US	4632

31846 7590 05/12/2008

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PATENT DEPARTMENT
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EXAMINER	
PALENIK, JEFFREY T	
ART UNIT	PAPER NUMBER
1615	

MAIL DATE	DELIVERY MODE
05/12/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/524,242	HURON ET AL.	
	Examiner	Art Unit	
	Jeffrey T. Palenik	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 March 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-5,7,8 and 18* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5,7,8 and 18* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *10 Feb 2005 and 15 Oct 2007*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Remarks

The Examiner thanks the Applicants for their timely reply filed on 18 March 2008, in the matter of 10/524,242.

Applicants' election **without traverse** of Group I, claims 1-5 and 7, is acknowledged.

The Examiner acknowledges Applicants' amendment to claim 8 such that it no longer improperly depends from cancelled claim 6, but now properly depends from claim 1. As such, claim 8 will be allowed into consideration for examination on the merits with the other claims of Group I.

The Examiner further acknowledges Applicants' elected species (i.e. Example 1b, page 22 of the instant specification), but respectfully submits that no requirement for an election of species was set forth in the previous action. Thus, the claims elected for examination on the merits will not be considered in light of the species.

The claims 1-5, 7 and 8 are presented and represent all claims under consideration.

Information Disclosure Statement

Two Information Disclosure Statements filed 10 February 2005 and 15 October 2007 are acknowledged and have been reviewed.

Specification

Applicant is reminded of the proper content of an abstract of the disclosure.

A patent abstract is a concise statement of the technical disclosure of the patent and should include that which is new in the art to which the invention pertains. If the patent is of a

basic nature, the entire technical disclosure may be new in the art, and the abstract should be directed to the entire disclosure. If the patent is in the nature of an improvement in an old apparatus, process, product, or composition, the abstract should include the technical disclosure of the improvement. In certain patents, particularly those for compounds and compositions, wherein the process for making and/or the use thereof are not obvious, the abstract should set forth a process for making and/or use thereof. If the new technical disclosure involves modifications or alternatives, the abstract should mention by way of example the preferred modification or alternative.

The abstract should not refer to purported merits or speculative applications of the invention and should not compare the invention with the prior art.

Where applicable, the abstract should include the following:
(1) if a machine or apparatus, its organization and operation;
(2) if an article, its method of making;
(3) if a chemical compound, its identity and use;
(4) if a mixture, its ingredients;
(5) if a process, the steps.

Extensive mechanical and design details of apparatus should not be given.

Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

Claim Objections

The use of the trademark “Tenox 8” has been noted in this application. It should be capitalized wherever it appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1, 7 and 8 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 2-5 of copending Application No. 11/100,982. Although the conflicting claims are not identical, they are not patentably distinct from each other because each are drawn to a soft chew composition comprising flavoring, starch sugar and oil, all of which encompass the same ranges. Though not anticipatory, the recited moisture content ranges overlap one another and both compositions are prepared without being extruded. Additives which can be added to both compositions include pharmaceuticals such as

ivermectin and fenbendazole. Lastly, the flavoring limitations of claim 7 (instant claims) and claim 4 ('982) fully encompass one another.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 18 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. As amended, the instant claim set now includes claim 18 which recites specific constituents for the instantly claimed soft-chew pharmaceutical composition which further claim approximate percentage values for each component. After carefully examining Applicants' response to the Requirement for Restriction and the instant disclosure, the examiner respectfully submits that support for this amendment is lacking and the addition of said limitations is **new matter**. Specifically, the approximate limitations of the aforementioned new claim 18 are not set forth in the instant specification. The specification, including Example 1b on pp. 22-24, which is referred to in Applicants' Remarks as being the support for the added claim, has been carefully reviewed and sufficient support for the limitation "about" with respect to each of the claimed

constituents was not found. Although the Examiner acknowledges that the disclosed support recites similar numerical limitations, it is also respectfully submitted that the values disclosed in the example appear to be exact values rather than approximated (i.e. "about") values and thereby do not support the limitations of the instant new claim 18.

Claims 18 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a limited class of antioxidants, such as the ones set forth on page 15, paragraph 2, line 2 of the instant specification, does not reasonably provide enablement for the generic class of antioxidants (or fillers). The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims. The limitation "an antioxidant" is extremely broad and encompasses an extremely large class of agents. As set forth in the prior art, the website www.gillco.com teaches an embodiment of the antioxidant known as Tenox 8 to comprise 20% BHT (butylated hydroxytoluene). The website www.grokfood.com provides a list of additives classified as antioxidants as codified under the International Numbering System by the Farm Agricultural and World Health Organizations (FAO/WHO) and teaches BHT as being one of many different antioxidants which can be used in food and pharmaceutical formulations. To this end, given that the instant invention is drawn to a pharmaceutical soft chew composition which includes "an antioxidant" as part of the claimed formulation, the Examiner respectfully submits that one of ordinary skill in the art would be faced with an undue experimental burden in attempting to practice the invention commensurate in scope with the claims. That is, the instant invention is concerned with a broad range of potential antioxidants, as disclosed in the instant

specification, and an ordinary practitioner would need to undergo undue experimentation in order to create the instantly claimed composition without guidance from the prior art. As such, the disclosure of the instant specification is not sufficient to support the generic concept of "an antioxidant".

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 18 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The limitations recited in claim 18 lack sufficient antecedent bases within claim 1. It is unclear whether the particular compounds recited in claim 18 are meant to further limit the composition of claim 1 or are to be included in addition to those recited in claim 1, particularly since there is no language to suggest what the relationship is between the claims (i.e. "further comprising…" or "wherein the additive is…"). For example, claim 1 recites "a starch component" whereas claim 18 recites two compounds which are defined by Applicants' specification as being starches (e.g. glycerin and PEG_{3350}). Herein, for the purposes of examination on the merits, the Examiner interprets the limitations recited in claim 18, particularly the percentage values, as being approximations which may be optimized.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-5, 7, 8 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Christensen (United States Pre-Grant Publication 2001/0036464) in view of Monte (USPN 5,578,336) and Miller (USPN 5,439,924).

The instant claim 1 is drawn to a soft chew pharmaceutical formulation comprising percent a flavoring, a starch, a sugar, an oil and a first additive comprising an active ingredient and their percentage ranges including percentage of moisture. The term "moisture content" as recited in the instant claim 1, is interpreted broadly by the Examiner to mean percentage of water present in the formulation. Furthermore, the recitations "formed by knockout" and "is not an extrudate" in claim 1 are considered by the Examiner to be process limitations which hold no patentable weight with regards to the claimed composition (MPEP 2113). Dependent claim 2 is drawn to a composition which further comprises no greater than 3% of a stabilizer. Dependent

claim 3 is drawn to a composition which further comprises no greater than 40% of an emulsifier. Dependent claims 4 and 5 are drawn to compositions which further comprise a second and third additive, respectively, each of which may be in the form of a pharmaceutical, neutraceutical, vitamin or mineral. Dependent claim 7 is drawn to a composition which further comprises a particular flavor such as fruit, vegetable or artificial flavorings. Dependent claim 8 further limits the active additive ingredient to a particular active agent such as aspirin, ivermectin or praziquantel. Dependent claim 18 is drawn to a composition which recites specific components for the constituents recited in claim 1 and further claims a stabilizer, an emulsifier and an antioxidant and their percentages.

Christensen teaches a soft chewable oral delivery composition which contains one or more active ingredients (0.1-5%) as well as 10-50% starch, 0-40% oil, 5-25% sugar, and 5-20% water ([0006], [0028] and claim 1). Active ingredients taught include pharmaceuticals such as ivermectin, fenbendazole, penicillin, aspirin, and also include vitamins and minerals ([0017 and Example 3). Minor amounts of stabilizers, emulsifiers and flavorants are taught [0017]. Example 5 teaches the use of cherry flavoring (0.1%). Corn starch, soybean oil and sucrose are also taught ([0010], [0012] and [0014], respectively).

Christensen lacks teachings for: 1.) an antioxidant, 2.) the specific stabilizer, emulsifiers or flavorant of claim 18, and 3.) any of the recited percentages of claims 3 and 18.

Monte teaches soft candy confectionaries whose moisture content is 1-95% by weight of water (Abstract; col. 19, lines 51-53). Flavoring, emulsifiers (e.g. Glycerine and Tween-80), an antioxidant (e.g. Vitamin E) and multiple active ingredients (e.g. Vitamin A, niacinamide and pantothenic acid) are also taught as part of the compositions (Tables I and II). Starch, fructose

and peppermint oil are also taught in Table I. Fructose is taught as a sugar-based flavoring agent and peppermint oil is taught as an oil-based flavoring agent.

Monte also lacks teachings for 1.) the specific stabilizer, emulsifiers or flavorant of claim 18, and 2.) any of the recited percentages of claims 3 and 18.

Miller teaches chewable tablet oral dose forms (col. 6, lines 3-6) as well as soft and inherently, chewable gelatin capsules (col. 10, lines 35-40) which may contain one or more active agents including ivermectin and ivermectin derivatives (col. 6, lines 26-31). Examples 1 and 2, for example, teach a chewable tablet formulations which further include excipients such as sugar, starch, emulsifiers (e.g. PEG_{6000}), and stabilizers (e.g. magnesium stearate). Additional excipients which may be included in Miller's formulations include antioxidants, flavorings, and oils (col. 10, lines 1-5).

In view of the combined teachings of the prior art, one of ordinary skill in the pharmaceutical art would have been motivated to prepare a soft-chew pharmaceutical composition containing the active agents and additives as instantly claimed with a reasonable expectation of success since such a composition and the ingredients for the same are seen to be taught in the prior art. Such would have been obvious in the absence of evidence to the contrary since both Christensen and Monte teach chewable embodiments which comprise multiple overlapping pharmaceutically active agents and additives. Similarly, Christensen and Miller both teach chewable compositions which contain common active agents such as ivermectin and common additive components such as oils, sugars, starch, emulsifiers and stabilizers.

None of the references specifically teach PEG_{3350} (e.g. emulsifier) or a sweet apple and molasses flavoring, or any of the recited percentages as claimed by the Applicants. Since the values of each parameter with respect to the claimed composition are adjustable, it follows that each is a result-effective parameter that a person having ordinary skill in the art would routinely optimize. Optimization of parameters is a routine practice that would be obvious for a person of ordinary skill in the art to employ. It would have been customary for an artisan of ordinary skill, for example, to adjust the type and amount flavoring or to adjust the type and amount of emulsifier (e.g. PEG_{3350} versus PEG_{6000}) in order to best achieve the most appealing chewable formulation to for the intended end-user. Thus, absent some demonstration of unexpected results from the claimed parameters, optimization of any of these parameters would have been obvious at the time of Applicant's invention.

No claims are allowed.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey T. Palenik whose telephone number is (571) 270-1966. The examiner can normally be reached on 7:30 am - 5:00 pm; M-F (EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent

Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Jeffrey T. Palenik/
Examiner, Art Unit 1615

/MP WOODWARD/
Supervisory Patent Examiner, Art Unit 1615